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REPLY UNDER 37 C.F.R. § 1.116 – EXPEDITED PROCEDURE
EXAMINING GROUP 1653

VIA HAND DELIVERY JANUARY 23, 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Hastings et al. Attorney Docket No.: PF487

Application Serial No.: 09/466,778 Art Unit: 1653

Filed: December 20, 1999 Examiner: Mitra, R.

Title: Novel Hyaluronan-Binding Proteins and Encoding Genes

RESPONSE UNDER 37 C.F.R. § 1.116

Box AF
Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Official Action mailed October 23, 2001 (Paper No. 23), Applicants respectfully request reconsideration of the rejections in view of the following remarks. Applicants submit concurrently herewith (a) a Fee Transmittal Sheet (in dupl.); and (b) a Notice of Appeal from the Examiner to the Board of Patent Appeals and Interferences.

Claims 23-80 are pending.

I. Rejections Under 35 U.S.C. §§ 101 and 112, First Paragraph

The Examiner has rejected claims 23-80 under 35 U.S.C. § 101 because the invention is allegedly not supported by either a specific or substantial asserted utility or a well-established utility. *See* Paper No. 16, pages 2-3. In particular, the Examiner alleges that Applicants "fail to provide biological activity of the polypeptides claimed." The Examiner has further rejected claims 23-80 under 35 U.S.C. § 112, first paragraph,

because one skilled in the art would allegedly not know how to use the claimed invention, based on the supposed lack of either a specific substantial asserted utility or a well-established utility.

Applicants respectfully disagree and traverse these rejections.

In contrast to the previous Office Action, Applicants note that the Examiner is now questioning the credibility of the asserted utilities for the instant invention, rather than specificity and substantiality. At the same time, though, the Examiner does not address Applicants' prior argument regarding specificity and substantiality. Thus, based on the instant Office Action, Applicants are unsure as to which element or elements the Examiner contends are lacking under the Utility Guidelines, and request further clarification.

Applicants point out that the specification clearly asserts utilities for the claimed invention. In particular, as the Examiner acknowledged in Paper No. 10, the specifcaiton asserts that the BM-HABP of the present invention is structurally analogous to the TSG-6 family of hyaluronan-binding proteins, and should have similar biological activities to members of that family based on the shared structure. *See* page 20, lines 21-33 (as amended); Figure 8. Based on such asserted activities, and contrary to the Examiner's comments, the specification provides guidance to the skilled artisan to use the BM-HABP of the present invention for similar purposes as TSG-6, including but not limited to: binding hyaluronan, and playing a vital role in arthritis, anti-inflammatory activity, and the vascular injury response. *See id.*

Moreover, "[a]n applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101." M.P.E.P. § 2107.02(III)(A) at 2100-39; *see also In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974). Thus, the burden is on the Examiner to establish that it is more likely

than not that a person of ordinary skill in the art would not consider the utility asserted by Applicants to be specific, substantial, and credible. *See* M.P.E.P. § 2107 at 2100-30. Such a *prima facie* showing must contain (1) an explanation that clearly sets forth the reasoning used in concluding that the asserted utility for the claimed invention is not specific, substantial, and credible; (2) support for factual findings relied upon in reaching this conclusion; and (3) an evaluation of all relevant evidence of record, including utilities taught in the closest prior art. *See id.* The Examiner must establish why it is more likely than not that one of ordinary skill in the art would doubt *(i.e.,* "question") the truth of the statement of utility. *See id.*; *see also In re Cortright,* 49 U.S.P.Q.2d 1464, 1466 (Fed. Cir. 1999); *In re Brana,* 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). Indeed, the Utility Guidelines note that:

> Where an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being "wrong," even when there may be reason to believe that the assertion is not entirely accurate. Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion.
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> M.P.E.P. § 2107.02 at 2100-40.

For the reasons set forth below, the Examiner has not met this burden, and thus the rejection of the claims for lack of utility under 35 U.S.C. § 101 must be withdrawn.

In particular, the Examiner presents no support for the allegation that the asserted utility is not credible, instead arguing that Applicants have failed to provide evidence of biological activity. However, as stated above, the burden is on the Examiner to establish that the asserted utility is not credible, not on Applicants to prove that it is. Indeed,

Applicants point out that the Examiner has presented no evidence to disprove Applicants' asserted utilities for BM-HABP. The Examiner has made no showing, for example, that the asserted utility is inconsistent with the function of other family members. Nor has the Examiner identified a reference suggesting that BM-HABP has activities that do not correlate with the asserted utilities.

The Utility Examination Guidelines require an evaluation of the utilities taught in the closest prior art (in the instant case, TSG-6). However, the Examiner argues that no such evaluation is possible, as "Applicants have not provided any activity of the BM-HABP which can be correlated with the activity of Tao et al.'s protein." Applicants strongly disagree, and remind the Examiner that as discussed in the response to the last Office Action, both Tao et al. and the instant specification teach that their respective proteins will bind hyaluronan. Accordingly, the Examiner has not met the burden of making a *prima facie* showing that Applicants' asserted utility is not credible, in that the Examiner has failed to provide evidence sufficient to show that the above asserted utilities would be considered "false" by a person of ordinary skill in the art.

Further, the Patent Office has stated that utility can exist for therapeutic inventions "despite the fact that an applicant is at a very early stage in the development of a pharmaceutical product or therapeutic regimen based on a claimed pharmacological or bioactive compound or composition." M.P.E.P. § 2107.01(III). "Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans." *In re Brana,* 51 F.3d 1560, 1568 (Fed. Cir. 1995) (emphasis added). There is no need to prove that a correlation exists between a particular activity and an asserted therapeutic use of a

compound as a matter of statistical certainty or provide actual evidence of success in treating humans where such a utility is asserted. *See* M.P.E.P. §§ 2107.01(III) and 2701.03.

In view of the above, the presently claimed invention possesses specific, substantial, and credible utilities which constitute patentable utilities under 35 U.S.C. § 101. Because Applicants' assertions of utility are sufficient to satisfy the requirements of 35 U.S.C. § 101, it is respectfully requested that the Examiner's rejection of claims 23-80 under 35 U.S.C. § 101 be reconsidered and withdrawn.

With respect to the rejection under 35 U.S.C. § 112, first paragraph, the Federal Circuit has held that the utility requirement of 35 U.S.C. § 101 and the how to use requirement of 35 U.S.C. § 112, first paragraph, have the same basis, *i.e.*, the disclosure of a credible utility. *See In re Brana*, 51 F.3d 1560, 1564, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); *see also* M.P.E.P. § 2107(IV). As discussed above, the specification teaches specific and well-established utilities of the claimed invention, thereby enabling the skilled artisan to use the claimed polypeptides. Since the specification contains a detailed description of how to use the claimed polypeptides, and the specification describes specific and immediate utilities for the claimed invention, the claimed invention is enabled. Accordingly, it is respectfully requested that the Examiner's rejection of the claims under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

II. Rejection of Claims 31-32, 36-37, 41-44, 48-51, 55-68, and 72-77 Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 31-32, 36-37, 41-44, 48-51, 55-68, and 72-77 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to

particularly point out and distinctly claim the subject matter which Applicants regard as the invention. *See* Paper No. 16, page 4. In particular, the Examiner alleges that the claims are indefinite since Applicants "do not provide any information to support the functional properties of the claimed polypeptide fragments." The Examiner further states that "without knowing the activity of the antibodies raised from the polypeptide fragments how one can practice the invention without knowing the function of those antibodies."

Applicants respectfully disagree and traverse this rejection.

As discussed in the previous response, Applicants maintain that the instant claims are not limited to biologically active fragments, or to fragments with only particular activities. In particular, the Examiner has failed to provide any support for such an interpretation of the instant claims, or to identify a single claim limitation that requires a particular function or activity for the claimed polypeptides. It is improper, though, to read a limitation into a claim from the specification. *See, e.g.*, M.P.E.P. § 2111 at 2100-36 to 37; *In re Van Geuns*, 988 F.2d 1181, 26 U.S.P.Q.2d 1057 (Fed. Cir. 1993). In the instant case, the Examiner is not only improperly inserting a limitation into the claims, but is also rejecting those claims because the inserted limitation is alleged to be unclear. However, the scope of the claims as actually recited is clear.

Thus, as the claims do not contain any limitation requiring a particular function or activity for the claimed polypeptides, whether the polypeptides have such function or activity or not is irrelevant to the determination of whether the claims are definite under 35 U.S.C. § 112, second paragraph. While the scope of the claims is broader than those limited to biologically active fragments, the breadth of a claim is not to be equated with indefiniteness. *See* M.P.E.P. § 2173.04; *In re Miller*, 441 F.2d 689, 169 U.S.P.Q. 597 (C.C.P.A. 1971).

Accordingly, Applicants again assert that the pending claims fully meet the requirements of 35 U.S.C. § 112, second paragraph, and respectfully request that the Examiner's rejection of the claims under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

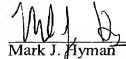
Conclusion

In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: January 23, 2002



Mark J. Hyman (Reg. No. 46,789)
Attorney for Applicants

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
Telephone: (240) 314-1224

Enclosures